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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,466	09/28/2004	Thomas William Bailey	PG4795USw	2240
23347	7590	02/03/2009	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			MINSKEY, JACOB T	
			ART UNIT	PAPER NUMBER
			1791	
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			02/03/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/509,466	<b>Applicant(s)</b> BAILEY ET AL.	
	<b>Examiner</b> JACOB T. MINSKEY	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,10-33 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,10-33 and 35-43 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/20/2007 and 09/28/2004</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Acknowledgement is made of Amendment received 9/25/07. Claims 1, 20-21, 24, 28, and 38-41 are amended, claims 3-9, 34, and 44-85 are cancelled.

### ***Claim Objections***

2. Claim 40 is objected to because of the following informalities: minor spelling error in line 4 "asssocited". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 10-33, and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Wilson et al, WO 00/71419 in view of Dworak et al USP 5,549,144.

7. Regarding claim 1, Wilson et al teaches a method of forming a tablet product (page 12 line 10 and figure 6 item 535), which comprises providing a perforate plate (figure 1a item 10 and page 9 line 20), each perforation extending from a first opening in a first side of the disk to a second opening on a second side of the disk (see figure 6); and a first director blade spaced from the first side of the disk (see figures 1-2); the method also comprising the step of:

- a) said first director blade with powder being disposed on the first side of the plate on a first path thereof which is different from the circular path (pages 10 lines 28-34);
- b) closing off one of the perforations in the disk by inserting a blanking pin into the perforation through the second opening (page 10 lines 25-28)

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d) directing powder into said closed-off perforation by the sweeping action of a first director blade pages 10 lines 25-35);

8. e) compacting said powder in the closed-off perforation by inserting a compaction pin into the closed-off perforation through the first opening, to form a tablet (page 12 lines 1-5); and

9. f) transferring said tablet from the perforation through the second opening of by withdrawing the blanking pin from the perforation through the second opening to reopen the perforation, and moving the compacting pin towards the second opening to transfer the compacted powder contents from the perforation (page 12 lines 7-15).

10. While Wilson et al teach that rotary systems are well known in the art (page 3 lines 13-14), the invention detailed does not teach that the perforated plate is a disk and has rotary movement, but it would have been obvious to one of ordinary skill in the art at the time of the invention to apply these teachings to a circular disk for ease of continuous operation.

11. In the same field of endeavor of compressing powder into tablets, Dworak et al teach that the perforated plate is in the form of a planar disk having plural perforations arranged in a circular path on the disk (see figure 2) a) having relative rotary motion of the perforate plate (see item A in figure 2 and column 3 lines 16-20) and the method further comprising the following steps while there is relative rotary motion (described in column 3 lines 13-20); c) directing powder from the first path onto the circular path (shown in figure 2 items 84 a and b and column 4 lines 23-35); d) directing powder on the circular path (figure 2 and items 84 and 86, column 4 lines 23-35).

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12. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Dworak's use of rotational motion in the Wilson method for the benefit of providing a continuous platform for the production of powder tablets.

13. Regarding claim 2, Wilson and Dworak remain as applied in claim 1 and Dworak further teaches that the first director blade is held static (stationary plows, column 4 line 25) and the perforated plate moves in rotary fashion relative thereto (shown in figure 2).

14. Regarding claims 10-13, Wilson and Dworak remain as applied previously and Wilson further teaches that the director blades are positioned at an acute angle, preferably at an angle of 5-25 degrees (page 3 lines 24-27), and that the first director blade presents multiple forward acute angles to the path of relative motion (page 3 lines 29-30).

15. Regarding claims 14-16, Wilson and Dworak remain as applied previously and Wilson further teaches that the blade can be flat, curved, or articulated (page 3 lines 29-30 and page 9 line 24 – page 10 line 5).

16. Regarding claims 17-19, Wilson and Dworak remain as applied previously and Wilson further teaches that a thin (from 4 to 8 mm) layer of powder is left on the perforated plate after movement of the first director blade (page 4 lines 9-11).

17. Regarding claims 20-23, Wilson and Dworak remain as applied previously and Wilson further teaches that the powder is further directed into the perforation by at least one subsequent director blade wherein the distance between the level of movement of the first director blade and the at least one subsequent director blade is 1 to 3 mm (page 4 lines 13-24).

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18. Regarding claim 24 Wilson and Dworak remain as applied previously and Dworak further teaches the step of removing excess powder from said circular path and directing the excess powder back to the first path subsequent to step d) (as shown by the plows in figure 2 and column 4 lines 23-35).

19. Regarding claim 24 Wilson and Dworak remain as applied previously and Dworak further teaches removing said excess powder by the action of a wiper (item 88 figure 2 and column 4 line 31).

20. Regarding claims 26-28, Wilson and Dworak remain as applied previously and Wilson further teaches that said tablet is transferred to a container by the action of a transfer pin by opening the perforation and transferring the tablet directly into the container (figure 6 and page 12 lines 7-15).

21. Regarding claims 29-30, Wilson and Dworak remain as applied previously and Wilson further teaches that the contents of the perforation are transferable by the action of a vacuum system that comprises a vacuum head and at least one vacuum cup (page 5 lines 14-16).

22. Regarding claims 31-33, Wilson and Dworak remain as applied previously and Dworak further teaches compressing to form a dense tablet (40-60% of original state, column 4 line 48).

23. Regarding claims 35-36, Wilson and Dworak remain as applied previously and Wilson further teaches that the transfer pin and the compacting pin are integral and identical (page 5 lines 26-28).

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24. Regarding claims 37-39, Wilson and Dworak remain as applied previously and Wilson further teaches that container is a blind cavity with a lid selected from the group consisting of a blister pocket, an injection molded plastic pocket, a capsule and a bulk container (page 5 line 30- page 6 line 2).

25. Regarding claim 40, Wilson and Dworak remain as applied previously and Wilson further teaches loading plural blisters arranged in series on an elongate blister strip with a tablet wherein the perforations are arranged in a series on the circular path and each perforation is associated with its own blanking pin and compacting pin (page 12 line 29- page 13 line 18 and figures 7-8b) and wherein the method comprises: closing off each perforation with its associated blanking pin in step b) (page 12 line 30 and figure 8a) directing powder into each closed-off perforation in step d) by the sweeping action of the first director blade (page 13 line 3); compacting said powder in each closed-off perforation in step e) by inserting the associated compacting pin into the closed-off perforation through the first opening to form a tablet (see figure 8b); and transferring said tablet from the second opening of each perforation to a corresponding blister of said elongate blister strip, in step f) by withdrawing the associated blanking pin from each perforation through the second opening and moving the associated compacting pin towards the second opening (see figure 8b and page 13 lines 14-18).

26. Regarding claim 41, Wilson and Dworak remain as applied previously and Wilson further teaches that in step f) each perforation of the perforated plate is serially brought into registration with the corresponding blister of the blister strip (page 12 line 29- page 13 line 18 and figures 7-8b).



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27. Regarding claim 42, Wilson and Dworak remain as applied in claim 41 and Dworak further teaches that at registration, the perforated plate is rotating and the blister strip is moving on a linear path (as shown in figure 2 items 38, and 48, column 2 line 65 – column 3 line 12).

28. Regarding claim 43, Wilson and Dworak remain as applied previously and Wilson further teaches that the tablet product comprises a medicament (page 6 line 4).

### ***Double Patenting***

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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30. Claims 1, 10-20, and 37-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-16, and 20-22 respectfully of U.S. Patent No. 7,426,815 in view of Dworak et al USP 5,549,144.

31. Claim 1 of USP 7,426,815 teaches all the limitations of claim 1 of the instant specification except for the direction of the movement of the plate. USP 7,426,815 teaches a linear movement while the instant application teaches rotational movement.

32. In the same field of endeavor of compressing powder into tablets, Dworak et al teach that the perforated plate is in the form of a planar disk having plural perforations arranged in a circular path on the disk (see figure 2) a) having relative rotary motion of the perforate plate (see item A in figure 2 and column 3 lines 16-20).

33. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Dworak's use of rotational motion in the instant method for the benefit of providing a continuous platform for the production of powder tablets.

34. The remaining presented claims are verbatim equivalents of the claims from USP 7,426,815.

### ***Conclusion***

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

36. USP 3,554,412 to Hayashi et al teaches a rotary disc with traps for forming capsules.

37. USP 4,542,835 to Gamberini teaches a method of forming uniform tablets by compression pins on a rotary plate.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB T. MINSKEY whose telephone number is (571)270-7003. The examiner can normally be reached on Monday to Friday 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven P. Griffin/  
Supervisory Patent Examiner, Art  
Unit 1791

JTM